Therapeutic Substances Act 1956

1956 CHAPTER 25

PART I

CONTROL OF MANUFACTURE AND IMPORTATION OF CERTAIN THERAPEUTIC SUBSTANCES

1 Substances to which Part I applies

The substances to which this Part of this Act applies are the substances specified in the First Schedule to this Act and any other therapeutic substances which may from time to time be added to that Schedule by regulations made under this Part of this Act as being substances the purity or potency of which cannot be adequately tested by chemical means.

2 Restrictions on manufacture of substances to which Part I applies

(1) No person shall manufacture for sale a substance to which this Part of this Act applies unless he holds a licence for the purpose from the licensing authority, or elsewhere than on the premises in respect of which such a licence is in force.

(2) A licence under this section shall continue in force for such period as may be prescribed, but may from time to time be renewed for a like period, and may extend to all the substances to which this Part of this Act applies, or to such one or more of them as may be specified in the licence, and shall be issued subject to such conditions as may be prescribed.

(3) An applicant for a licence or the renewal of a licence must satisfy the licensing authority that the conditions under which the substances are to be manufactured by him and the premises in which they are to be manufactured are such as to comply with any regulations made under this Part of this Act, and an applicant who so satisfies the licensing authority shall be entitled to the grant or renewal of the licence.

(4) The licensing authority may revoke a licence or suspend it for such period as he thinks fit if, in his opinion, the licensee has failed to comply with the conditions subject to which the licence was issued or with the regulations made under this Part of this Act as to the prescribed standards of strength, quality and purity, and such revocation or

suspension may apply to all the substances to which the licence applies or to some one or more of them:

Provided that a person who is aggrieved by the revocation or suspension of his licence may appeal to the High Court, whose decision shall be final.

(5) Nothing in this section shall apply to the preparation by a duly qualified medical practitioner for any of his own patients or for and at the request of another such practitioner of a substance to which this Part of this Act applies, if it is specially prepared with reference to the condition, and for the use, of an individual patient.

(6) In the application of this section to Scotland, for the reference to the High Court there shall be substituted a reference to the Court of Session.

3 Restrictions on importation of substances to which Part I applies

(1) The importation of a substance to which this Part of this Act applies is hereby prohibited unless the substance—

(a) is proved to the satisfaction of the licensing authority to comply with the standard of strength, quality and purity prescribed in the case of that substance, if the substance is one the manufacture of which is carried on in the United Kingdom, or, if such manufacture is not so carried on, with such standards (if any) of strength, quality and purity, as may be prescribed for that substance, or, if no such standards are so prescribed, with such standards of quality and purity as are prescribed in the case of therapeutic substances of a similar class the manufacture of which is carried on in the United Kingdom, and is consigned to a person licensed by the licensing authority to import it; or

(b) is consigned to a person engaged in scientific research holding a special licence to import it for the purpose of such research issued by the licensing authority.

(2) The issue of a licence under this section shall be subject to such conditions, including conditions as to suspension and revocation, as may be prescribed.

4 The joint committee and the advisory committee

(1) For the purpose of framing regulations under this Part of this Act and for securing uniformity of standards, there shall be established a joint committee consisting of the Minister of Health, who shall be chairman, the Secretary of State, and the Minister of Health and Local Government for Northern Ireland:

Provided that each member of the joint committee may appoint a deputy to act for him at meetings of the committee at which he is unable to be present.

(2) For the purpose of assisting the joint committee in the framing of regulations under this Part of this Act, there shall be appointed an advisory committee consisting of one member appointed by the Minister of Health, who shall be chairman, one member appointed by the Secretary of State, one member appointed by the Minister of Health and Local Government for Northern Ireland, one member appointed by the Medical Research Council, one member appointed by the General Medical Council, one member appointed by the British Medical Association, one member appointed by the Council of the Pharmaceutical Society of Great Britain, and one member appointed by the Council of the Royal Institute of Chemistry.

5 Power to make regulations

(1) The joint committee, after consultation with the advisory committee, may make regulations for the following purposes;—

(a) for prescribing the standard of strength, quality and purity of any substance to which this Part of this Act applies;

(b) for prescribing the tests to be used for determining whether the standard prescribed as aforesaid has been attained;

(c) for prescribing units of standardisation ;

(d) for adding to the First Schedule to this Act any therapeutic substance the purity or potency of which cannot be adequately tested by chemical means;

(e) for prescribing the form of licences under this Part of this Act and of applications therefor, and of notices to be given in connection therewith;

(f) for prescribing the conditions subject to which licences may be issued, including, in the case of a licence to manufacture, conditions that the licensee shall allow any inspector authorised by the licensing authority in that behalf to enter any premises where the manufacture is carried on, and to inspect the premises and plant and the process of manufacture and the means employed for standardising and testing the manufactured substance and to take samples thereof ;

(g) for excluding from the operation of this Part of this Act, or of any of the provisions thereof, any substance intended to be used solely for veterinary purposes ;

(h) for prescribing any other matter which under this Part of this Act is to be prescribed.

(2) Regulations so made may also, as respects any such substance to which this Part of this Act applies as may be specified in the regulations, contain provisions—

(a) requiring that, if advertised or sold as a proprietary medicine or contained in such a medicine, such accepted scientific name, or name descriptive of the true nature and origin of the substance, as may be prescribed shall appear on the label;

(b) requiring that the date of the manufacture shall be stated in the prescribed manner on all vessels or other packages in which the substance is sold or offered for sale, and prohibiting the sale of the substance after the expiration of the prescribed period from the date of manufacture;

(c) prohibiting the sale or the offering for sale of the sub stance otherwise than in a vessel or other container of such character as may be prescribed, and requiring that the prescribed label or other description shall be affixed to the vessel or other container in which the substance is sold or offered for sale.

6 Offences under Part I

A person who—

(a) being a person who is required by this Part of this Act to be licensed in that behalf manufactures for sale a substance to which this Part of this Act applies without a licence for the purpose, or elsewhere than on premises in respect of which a licence is in force;

(b) contravenes or fails to comply with a condition subject to which a licence under this Part of this Act is issued ; ,

(c) sells or has in his possession for sale a substance to which this Part of this Act applies knowing it to have been manufactured or imported in contravention of this Part of this Act or the regulations made thereunder;

(d) contravenes or fails to comply with the provisions of any regulation made under this Part of this Act;

shall be guilty of an offence under this Part of this Act and liable, on summary conviction, to a fine not exceeding one hundred pounds or, in the case of a second or subsequent conviction, to such a fine or to imprisonment for a term not exceeding three months, and in either case to forfeit any goods in connection with which the offence was committed, and without prejudice, if the offender is the holder of a licence, to the power of the licensing authority to revoke or suspend the licence.

7 Licensing authority for purposes of Part I

The following authorities shall be the licensing authorities for the purposes of this Part of this Act:—

(a) as respects England and Wales, the Minister of Health;

(b) as respects Scotland, the Secretary of State ;

(c) as respects Northern Ireland, the Minister of Health and Local Government for Northern Ireland.